



DEPARTMENT OF HEALTH & HUMAN SERVICES

m 2640m

New York District
Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

May 13, 1999

WARNING LETTER NYK 1999-43

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jerome B. Heims, President
Baltimore Fish & Oyster, Inc.
792 Genesee Street
Buffalo, NY 14211

Dear Mr. Heims:

An inspection of your facility was performed March 1-2 & 5, 1999, by U.S. Food and Drug Administration (FDA) Investigator Joseph A. Famiglietti. The inspection revealed various seafood products, including fresh Blue Marlin Loins, processed at, and distributed from, your facility, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. They are adulterated because they were processed and held under conditions contrary to 21 CFR 123 which constitute insanitary conditions whereby they may have been rendered injurious to health.

As we explained in previous letters to you, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: **(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of seafood products, including fresh Blue Marlin loins, deviates from the regulations contained in 21 CFR 123 as follows:

- Failure to control the histamine hazard at the critical control point (CCP) "Receiving" for your histamine-producing species, including Blue Marlin [21 CFR 123.6(b)]. The procedure included in your HACCP plan for assuring incoming product was maintained at appropriate temperatures during transport, is not being followed. The procedure requires that prior to accepting shipments which include histamine-producers, a letter be on file from the transporter that *guarantees* the temperature of the products was maintained at 40°F or below during transport. The letter your firm has on file from the transporter includes no such guarantee.

Baltimore Fish & Oyster, Inc.

Page 2

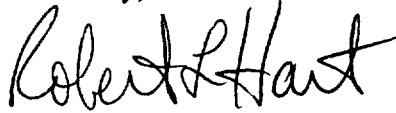
- The HACCP plan used for coverage of fresh Blue Marlin failed to list the species related food safety hazard of histamines. Although Blue Marlin is a histamine-forming species, your firm was covering it under a HACCP plan for non-histamine producers [21 CFR 123.6(c)(1)].

- Monitoring procedures implemented at the CCP "Receiving" are inadequate for Blue Marlin [21 CFR 123.6(b)]. For six of eight shipments containing Blue Marlin received at your firm from 1/12/99 to 3/2/99, your firm had no documentation to indicate product temperature checks were performed on Blue Marlin.

You should take prompt action to correct these and all violations at your firm. Failure to achieve prompt corrective action may result in further regulatory action - without further notice. These actions include seizure and/or injunction.

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted deficiencies and to prevent a recurrence of similar violations. Your written response should be directed to James M. Kewley, Compliance Officer, at the above address. Mr. Kewley can be reached at (716) 551-4461, ext. 3128.

Sincerely,



Brenda J. Holman
District Director

